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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,607	12/17/2001	Ni Ding	10177-103	5308

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EXAMINER	
LANDREM, KAMRIN R	
ART UNIT	**PAPER NUMBER**
3738	8

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,607	DING ET AL.	
	Examiner	Art Unit	
	Kamrin R. Landrem	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 8, 10-12, 14, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (USPN 5,545,208) in view of Hossainy et al (USPN 6,558,733 B1).

Wolff, as discussed in the previous office action, discloses an expandable (by balloon or self-expanding, Column 10) metal stent with openings (Figure 1) with a coating of hydrophobic biostable elastomeric material (6:60-63) and a biologically active material such as Heparin (5:41) or drug (Column 6, lines 60-63) that conforms to the structure and preserves the openings of the stent (Figures 12 and 13). Wolff discloses the expandable stent as claimed however Wolff fails to teach that the stent is prefabricated before it is coated. Hossainy et al teaches the method of producing a drug delivering stent by using a prefabricated (11:37) stent 10 that is etched and then coated with therapeutic substances (4:37+) to provide a stent with improved drug delivery capabilities. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method disclosed by Hossainy by using a prefabricated stent to produce the coated expandable stent as disclosed by Wolff.

similar to applicants spec on 9.15-35

Claims 2, 4, 5, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff as modified by Hossainy, further in view of Lambert (USPN 5,900,246).

Regarding claim 2, Wolff, as modified, discloses of a prefabricated stent that is coated but lacks the teaching of the thickness and composition of the coating. Lambert teaches of a stent with a polyurethane coating that has a thickness between 25 and 500 microns to vary the degree of swelling of the coating for drug release (Column 4, lines 27-30), overlapping the ranges disclosed by the applicant. Lambert further teaches that the composition of the polymer coating can have a 1:20 or 5% ratio of solvent to non-solvent to achieve the desired rate of evaporation (Column 4, lines 36-52), falling within the 4 to 6% range disclosed by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wolff to specify the thickness and composition of the coating in order to account for swelling and solubility of the compounds within the coating.

Claims 6, 7, 9, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff as modified by Hossainy, further in view of Berg et al. (USPN 5,464,650).

Regarding claims 6, 7, 9, 17, 18 and 20 Wolff as modified discloses a prefabricated stent that is coated, however they lack the teaching of how the stent is coated. Berg et al. teach of a stent made of tantulum or stainless steel (Column 3, Lines 35-40) that is coated by a spraying method while being rotated (Column 5, Example 1). Berg et al. further teach that the stent is coated while in the expanded position (Column 6, Example 7). Therefore, it would have been obvious to one of ordinary skill in the art at

the time the invention was made to modify the invention of Wolff et al. to have the metallic stent made of stainless steel, titanium or another metal for strengthened physical properties, and to coat the stent while rotating it in an expanded state to ensure a coating of even thickness.

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (USPN 5,900,246) in view of Hossainy.

Lambert teaches a metallic stent (3:51) that has a coating of 25 to 500 microns in thickness (4:28), comprising a biostable elastomeric material (polyurethane) and a biologically active material (dexamethasone) (Column 3). Lambert discloses the stent as claimed however Lambert fails to teach that the stent is prefabricated. Hossainy teaches an expandable prefabricated (7:57) metal (4:18-22) stent 10, that is coated with a biologically active material (4:38+), having a tubular body and a sidewall structure having openings (see Figures 1-4), the openings free from any coating. Therefore in view of the teachings it would have been obvious at the time the invention was made to have modified the stent as disclosed by Lambert by using a prefabricated stent with openings free of coating as taught by Hossainy in order to provide a stent with improved drug delivery properties that allows for tissue ingrowth.

Regarding claims 26-28, Lambert teaches of a coated stent, however Lambert lacks the teaching of the process by which the stent is coated. However, the final product, a coated stent, is taught in the prior art and therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed coating process to apply a coating to the stent for anti-inflammatory purposes (see MPEP 2113).

Response to Amendment

The prior art as disclosed by Hossainy teaches a prefabricated stent that is coated with biologically active materials. Prefabricated stents are well known in the art and applicant's amendments to claims do not make the claims patentably distinguishable over the prior art.

Response to Arguments

Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738

KRL

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700